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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,796	01/11/2002	Naida M. Loskutoff	13511.1USU1	8344

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EXAMINER

AFREMOVA, VERA

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/044,796	<b>Applicant(s)</b> LOSKUTOFF ET AL.	
	<b>Examiner</b> Vera Afremova	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-14 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/24/02;7/01/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of the Group I, claims 1-14 and 21-23, in the response filed 12/05/2003 is acknowledged. The traversal is on the ground(s) that grounds for restrictions are not sufficient. This is not found persuasive for the reasons explained in the prior office action. Moreover, the claimed groups of inventions are distinct as they have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification and because the search required for one groups is not required for another group, restriction for examination purposes as indicated is proper. Therefore, the requirement is still deemed proper and is therefore made FINAL.

Claims 15-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant timely traversed the restriction requirement in response filed 12/05/2003.

Please, note. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101,

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102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Claims 1-14 and 21-23 are under examination in the instant office action.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 6, 7, 8, 11-14 and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 685 556 [IDS reference].

Claims are directed to a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolality of about 250-350 mOsm. Some claims are further drawn to the use of 90% water in the composition, to the use of 0.1-6.0% of non-animal derived phospholipid in the composition, to the use of freeze agent or

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glycerol at concentration 3-14% in the composition. Some claims are further drawn to incorporation of semen into the semen extender composition. Some claims are/are further drawn to the method of making the semen extender composition by mixing the components of the composition.

EP 0 685 556 discloses a semen extender composition which is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, a mixture of Tris and sodium citrate which act as both surfactant and buffer, carbohydrate such as glucose, fructose or lactose and freeze agent or glycerol (see page 3, lines 4-16). The amounts and /or concentrations of ingredients in the cited semen extender composition are within the ranges of the claimed semen extender composition. Although the cited patent is silent with regard to pH and osmolarity of the semen extender composition and/or solution for semen preservation, the values of pH and osmolarity which are claimed are regular parameters which are commonly used for animal cell culture maintenance and preservation. The cited EP patent also teaches the method of making the semen extender composition by mixing the components of the composition. The cited EP patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent EP 0 685 556 anticipates the presently claimed invention.

Claims 1-8, 10-14 and 21-23 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,368,786.

Claims 1-3, 6, 7, 8, 11-14 and 21-23 as explained above. Claims 4 and 5 are further drawn to incorporation of antioxidant or vitamin A into the semen extender composition. Claim

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10 is further drawn to incorporation of polyoxyethylene sorbitan (Tween 80) into the semen extender composition.

US 6,368,786 teaches a semen extender composition that is substantially free from animal products and comprises a non-animal derived phospholipid such as lecithin, surfactant, carbohydrate and buffer to provide for pH of about 6.9-7.2 and osmolarity of about 250-350 mOsm, for example: the diluent compositions as disclosed in the tables at col. 3 and 4. The diluent composition is identical to the composition of the cited above EP 0 685 556 (see example 4 of US'786). Further, the diluent composition of the US'786 comprises antioxidant or vitamin A dissolved in emulsifier such as Tween 80 (col. 1, lines 49-56). The cited US'786 also teaches the method of making the semen extender composition by mixing the components of the composition. The cited US patent also teaches incorporation of semen into the semen extender composition (example 3).

Thus, the cited patent US 6,368,786 anticipates the presently claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 685 556 [IDS reference] or US 6,368,786 [PTO form 892] taken with US 3,444,039 [IDS reference], US 6,130,034 [IDS reference], US 6,140,121 [IDS reference] and the reference by Hellmann et al. [1988, IDS reference 1].

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Claims 1-8, 10-14 and 21-23 as explained above. Some claims are further drawn to the use of surfactant such as sodium lauryl sulfate, to the use of antioxidant such as vitamin E in the semen extender composition.

EP 0 685 556 or US 6,368,786 are relied upon as explained above for the disclosure of semen extender compositions. They are lacking disclosure about the use of various surfactants and/or antioxidant vitamins.

However, the cited patent US 6,130,034 teaches incorporation of antioxidant such as vitamin E, for example: see col. 1, line 50, as a commonly used and/or regular component in the composition intended for semen transportation and storage (col.1, line 29).

The reference by Hellmann et al. teaches incorporation of sodium lauryl sulfate into composition intended for animal semen preservation (see abstract).

In addition, US 3,444,039 is relied upon to demonstrate that a sodium citrate buffering preparation provides for neutral pH of about 6 -7 and osmolarity of about 250-300 mOsm which are regular pH and osmolarity parameters commonly used for animal cell culture maintenance and preservation (see col. 2, line 6 or see col. 3, line 30 and 44). And the cited US 6,140,121 teaches incorporation of various buffers into compositions intended for semen preservation including buffers such as EDT (col. 19, line 28) or Tris or sodium citrate as well as polyxyethylene sorbitan which is Tween 80 within the medium M199 in the composition intended for freezing sperm (col. 16, lines 57-59).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to incorporate ingredients such as various antioxidants and various surfactants into the semen extender composition as required by the presently claimed

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invention with a reasonable expectation of success in obtaining composition suitable for semen maintenance and/or preservation because these compositions and ingredients have been known and commonly used in the field of semen maintenance and preservation as adequately demonstrated by the cited references in combination. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova

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February 5, 2004



VERA AFREMOVA

PATENT EXAMINER